



REGULATORY OBSERVATION

CHINA COMPLIANCE

OCT to DEC 2021

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China IT/ICT Watch November and December 2021

1. [Consumer Goods] - SEP 2, 2021, Excessive Packaging Banned in China

On September 2, 2021, the Requirements of Restricting Excessive Package-Foods and Cosmetic (hereinafter referred to as “the Requirements” GB 23350-2021) is a revision for the national standard GB 23350-2009 that was issued by State Administration for Market Regulation (SAMR) and Standardization Administration of China (SAC).

The Requirements is a national mandatory standard that was developed for the purpose of controlling excessive packaging. The goal is to protect consumer rights and reduce environmental pollution caused by the unnecessary packings.

The first version of the Requirements was published in 2009. In its latest version, the critical contents are summarized as follows:

1. Cover an administrative scope of 31 kinds of foods and 16 types of cosmetics.
2. Strictly regulate the number of layers allowed for different product categories.
3. Modify the definition of several technical terms and add in a new definition term called “multiple products” to regulate packing requirements for gift boxes with various types of products.
4. Change the calculation measures for critical parameters such as interspace ratio
5. Specify necessary spatial coefficient of commodity for different goods.

The new version of the standard still requires all packing costs, unless in direct contact with the product, not exceed 20% of the selling price. It will be rolled out in September of 2023, leaving a 2-year transition period for all manufacturers and enterprises involved

With the announcement of the new standard version, related MNCs and foreign manufactures are suggested to start a transition process if current products do not comply with the Requirements. The SAMR also stated that more training or interpretations on the Requirements will be organized to help relevant parties, so MNCs who have already entered the Chinese market should follow-up on such information and participate in the courses to fit in.

2. [Automotive - Green] - Acceleration Expected in China Carbon Emission Standard

On August 24, 2021, in response to the proposal of the Chinese People's Political Consultative Conference (CPPCC) regarding vehicle emission standardization system, Ministry of Industry and Information Technology (MIIT) released an article to further specify work plans on the topic.

MIIT's next steps to enhance carbon emission standardization system include:

1. Articulate roadmap on carbon peak and carbon neutral for automotive industry.

A detailed low-carbon development roadmap will be drawn to carry out full-life carbon emission calculations. Its evaluation results will be used to determine specific industrial carbon peak goals. Policies and practical methods will be raised in various low carbon aspects (product, transportation, energy etc.) to actively contribute to the final goal.

2. Specify more innovative low-carbon technologies for automotive and set up specialized R&D projects.

Set up national innovation centers on battery, ICV etc. to make critical technological breakthroughs.

Make joint efforts with the Ministry of Science and Technology to both implement the key project of a new energy vehicle, stated in "14th Five Year Plan," and initiate the investigation and preparation for Phase VII emission standard.

3. Establish a more comprehensive policy and standardization system to support automotive industry on achieving carbon peak and carbon neutral.

Following the published national mandatory standards on car emission (e.g.: GB 19578-2021 Fuel Consumption Limits for Passenger Cars), more standards will be developed and issued in the sector.

4. Facilitate the coordination and cooperation of automotive industry with other industries.

Push forward the data and information exchange among cross-sector administrations to form a highly efficient interaction system. Improve combined development of a transportation network that covers multiple elements (vehicle, road, people, cloud) and to finally form an integrated intelligent transport service.

All in all, MIIT will follow the New Energy Automobile Industry Development Plan (2021-2035) and its guidelines. The Ministry should take full advantage of the existing joint meeting mechanism for energy-saving and new energy vehicles between relevant ministries to set up more specific measures and policies to achieve the carbon peak and carbon neutral goals.

Based on the published working goals of MIIT for vehicle emission management, we advise MNCs and foreign manufacturers in China market proactively accelerate their carbon-neutral efforts and R&D plan. For the enterprises who already released their carbon neutral roadmap, it could be necessary to keep observing the future official roadmap/plan releasing by MIIT on vehicle emissions to ensure compliance. Manufacturers of traditional petroleum/diesel vehicles might endure more impact than the new energy vehicle producers, as well.

3. [Green] - SEP 15, 2021, Comments Solicited for Emission Peak Related Sector Standards

On September 15, 2021, the Ministry of Industry and Information Technology (MIIT) solicited opinions on a series of sector standards related to emission peak, including the Technical Specification for Carbon Emission Verification in the Petroleum and Chemical Industry. The 197 industry standard projects cover 11 fields, including chemical, steel, building materials, electronics, textiles, and communications. Of the 197 standard projects, 111 are about chemical, steel and building materials.

The 197 projects are all related to green energy saving, including carbon emission quota, carbon footprint, carbon disclosure, management standards, waste recycling, as well as green factories and recycling parks. Among the 197 standards, 195 are newly developed plans and 2 are revised plans. All of the

released standards in this batch do not adopt international and foreign advanced standards.

In September 2020, China announced their dual carbon goals (carbon peak and carbon neutrality). A number of related measures have been introduced since then, such as the 14th Five-year Plan for Circular Economy and the opening of China's carbon trading market in July 2021.

Currently, the carbon trading market continues to thrive with its total volume of carbon emission quota (CEA) exceeding 5.9 million tons in its first month. In addition to the power generation companies that initially entered the carbon market, building materials, steel, non-ferrous metals and other industries are encouraged to

participate in the carbon market later. Therefore, the purpose of this batch of sector standards is to provide reference for China's carbon market and various industries (such as emission reduction and carbon footprint, etc.).

In addition, the accuracy of carbon emission data is crucial for both the climate change and carbon market. As a result, the standards for carbon disclosure and carbon footprint verification play an important role in ensuring the reliability and accuracy of carbon emission data. There are no relevant sector standards for carbon footprint before, so the formulation and release of these sector standards will fill the gap in this field.

Recently, emission reduction became an important topic in China. With the opening of the carbon market and the fact that some Chinese regions went through electricity restrictions in August, we'd suggest foreign stakeholders pay more attention to the green topic. For foreign companies that have entered or intend to enter the Chinese market, especially those who rely heavily on traditional energy in production process, we advise that they start to prepare for the energy transition according to carbon reduction standards and initiatives; companies that produce products driven by traditional energy sources (diesel, gasoline, non-road equipment, etc.) should also focus on the direction of emissions-related policies in China and change their strategy in time.

4. [Cybersecurity] – SEP 13, 2021, Official Filing Measures on Network Product Vulnerability Out for Comments

On September 13, 2021, the Ministry of Industry and Information Technology (MIIT) called for comments on the Administrative Measures for the Recordation of Network Product Security Vulnerability Collection Platforms (hereinafter referred to as "the Measures").

The key messages are as follows:

- The network product security vulnerability collection platform mentioned in the Measures refers to the platform established by relevant organizations or individuals to collect the security vulnerabilities of other network products, except for those that are only used to repair their own network products, network and security vulnerabilities in the system.
- The filing of vulnerability collection platforms is conducted by the cyber security threats and vulnerability information sharing platform of MIIT through online filing methods.

5. [Chemicals] – AUG 20, New Regulations on Chemical Substances of Consumer Products

On August 20, 2021, the National Consumer Product Safety Standardization Technical Committee (SAC/TC 508) issued a recommended national standard - Guidelines for the Development of Chemical Substances Limit in Consumer Goods (Call for comments) (hereinafter referred to as The Standard), calling for public opinions until October 20, 2021.

During the production process of The Standard, SAC/TC 508 studied Chinese as well as foreign laws and regulations on: product quality and safety, risk management and quality level. In addition, the Committee also learned from general practices within the United States, European Union and from members of the Organization for Economic Cooperation and Development (OECD). They compared and analyzed the relevant standards and guiding documents together with the differences between the planning process of China and other foreign countries. To collect the toxicity, function and other information of chemical substances, The Standard searched and studied information from professional databases including the International Chemical Security Project Database (IPCS), Integrated Risk Information System (IRIS) of American Environmental Protection Agency (EPA), International Toxicity Estimates for Risk (ITER), and the American Agency for Toxic Substances and Disease Registry (ATSDR).

The Standard also takes standards such as the General Principles for Risk Assessment of Chemicals (GB/T 34708-2017) and the General Principles for Risk Assessment of Consumer Product Safety (GB/T 22760-2008) into consideration.

The Standard gives a clear definition of consumer products and stipulates the process of developing a chemical substances limit in consumer products (including home appliances, toys, stationery, and household goods). The process is divided into four steps:

- a) Collect chemical substance information: including toxicity, function, product use outlines, who will use the products, and the production and application of the chemical on the industrial chain;
- b) Determine the value of the chemical substance limits for consumer products in accordance with current standards/regulations or risk assessment methods;
- c) Analyze and evaluate the impact on consumers, industries and other aspects with the determined chemical substances limit;
- d) Finalize and set up the limit based on all the analyses above.

This standard will regulate and guide organizations to carry out activities relevant to the development of chemical substance limits in consumer products. BESTAO suggests that manufacturers in relevant industries both review the chemical substances in current related products based on the standard draft and keep up with the standard issuance in order to take compliance actions accordingly.

6. [Automotive] – JUL 26, 2021, Two Inspection Codes Issued for Transportation-related Products

On July 26, 2021, the Ministry of Transport of the People's Republic of China issued two supervision and spot check rules for two sectors of transportation-related products. Details of the two documents are as follows:

1. Implementation Code of Industrial Quality Supervision and Spot Check for Satellite Positioning Vehicle-Mounted Terminals on Road Transport Vehicles.

It applies for four kinds of vehicle-mounted vehicles: passenger, freight, vehicle for transport dangerous goods and trailers. It articulates specific testing requirements (sampling method, quantity and disposal etc.), along with the specifications and testing method. The document also provide the forms used in the testing process.

2. Implementation Code of Industrial Quality Supervision and Spot Check for Plastic Bellows Used For Pre-stressed Concrete Bridges

This implementation code is the benchmark for transportation administrations on all levels to carry out quality supervision on this product. The code depicts all necessary aspects for the supervision and review process, including: product category, definitions, testing principle, sampling requirements, scoring and evaluation rules etc.

The documents have come into force as of the publishing date. Such product manufacturers within the Chinese market share are advised to double check current product specifications to make compliance actions if necessary. MNCS whose products or equipment are in use of such goods are suggested to check with suppliers on the to-be-shipped orders to make sure all arriving components/products fit the quality supervision requirements.

7. [ICT] - AUG 4, 2021, Assessment Methods for Machine Learning Algorithm out for Public Comments

On August 4, 2021, the National Information Security Standardization Technical Committee of China (SAC/TC 260) issued a nationally recommended standard, Information Security Technology-Security Specification and Assessment Methods for Machine Learning and Algorithms (hereinafter referred to as “the Standard”) to call for public comments.

The Standard was proposed and developed by SAC/TC 260, and was drafted in accordance with Directives for standardization-Part 1: Rules for the structure and drafting of standardizing documents.

The Standard gives the terms and definitions related to machine learning algorithm. It also specifies the security requirements and confirmation methods of machine learning algorithm in different stages (including design and development, verification and test, deployment and operation, maintenance and upgrading, and decommissioning and offline process). The document clarifies the implementation of security assessments on machine learning algorithm as well. Within the Standard, a security assessment index system, machine learning algorithms, security risks and sample of attacks can also be found.

Machine learning algorithm security includes both the security of the algorithm itself and the security of the

algorithm application. Therefore, according to the machine algorithm application in real life, the Standard divides the security requirements of machine learning algorithm into 2 levels, which are applicable to different scenarios as follows:

--Basic level: applicable to machine learning algorithms in all scenarios;

--Enhancement level: applicable to important fields such as public services, transportation, financial services, health care, welfare and education. Additional security requirements are necessary for the decision-making of key matters including the security of people's lives and properties and protection of individual rights.

This document applies to the security assessment of algorithms in machine learning systems. Machine learning system developers and operators can also use the Standard to carry out self-assessment and make improvements during the development and operation process. It is recommended that relevant enterprises assess the algorithm at different stages when they deal with machine learning systems, and make compliance adjustments if necessary according to the corresponding security requirements. BESTAO will follow up on the release of the final document and keep track of its revision to provide the latest information.

8. [Medical] - OCT 15, 2021, New Medical Technical Guidelines Out for Public Comments

On October 15, 2021, National Medical Products Administration (NMPA) Centre for Drug Evaluation (CDE) is calling for comment until 15 Nov 2021 on Technical Guiding Principles on Human-specific Immunoglobulin Pharmaceutical Research and Evaluation.

The document's main contents cover:

- Summary
- Scope of application
- General principles
- Pharmaceutical research and evaluation key points
- Terminology
- References.

9. [Green] - OCT 17, 2021, MEE Raised the Bar on EIA for Industrial Parks

On Oct 17, Ministry of Ecology and Environment (MEE) released *Notice on Launching Carbon Emissions Assessment Pilots as Part of EIAs* (Environmental Impact Assessment) for industrial park plans. In this official notice, following contents and requirements are mentioned:

- Objectives
 - o create a set of repeatable, generalisable instances of incorporating carbon emissions assessments into EIA systems
 - o incorporate climate change factors into environmental management and 'high-quality development'
- Pilots
 - o industrial parks that have the capacity to assess carbon emissions will be the focus of pilots
 - o list of pilot parks are specified along with the document
- Work tasks
 - o explore technical methods of assessing carbon emissions in EIAs

- o refining environmental management mechanisms for incorporating carbon emissions assessments into EIAs
 - o creating a set of repeatable, generalisable instances of incorporating carbon emissions assessments into EIA systems
- Guarantee measures
 - o organising implementation
 - o strengthening capacity building
 - o strengthening publicity

Appendices are provided the list of parks for the pilots and an explanation of work priorities.

10. [Automotive] – OCT 28, 2021, Five Rectified Automotive Standards Rolling-out Soon

On October 28, 2021, MIIT issued a notice on Rectification of Five Standards. Standards listed will enter into force from Jan 1, 2022.

All of the five standards are mandatory, and the standard names are listed as follows:

GB 18384-2020 Electric vehicles safety requirements

GB 38031-2020 Power batteries for electric vehicles safety requirements

GB 38032-2020 Electric buses safety requirements

GB 39732-2020 Automatic vehicle events data recording system

GB 7258-2017 Technical conditions for the safe operation of motor vehicles

The rolling-out of the 5 standards means all the type approval models applied for these standards must conform to all the requirements within, otherwise they would not be able to enter the market for sale. All relevant manufacturers should check the current product line and ensure compliance accordingly to avoid risks.

11. [Automotive] - NOV 3, 2021, Passenger Vehicles Facing Stricter Declaration Requirements in China

On November 3, 2021, Ministry of Industry and Information Technology (MIIT) published Notice on Regulating Declaration Requirements for the Entry of Passenger Vehicles (hereinafter referred to as “the Notice”) to provide implementing details for the Guiding

Opinions on Promoting High-Quality Development of Rural Passenger Transport (jointly released by nine ministries on August 9, 2021).

In the Notice, MIIT requires vehicle companies to:

provide the following information on the relevant baggage storage area, as access to passenger vehicles with luggage areas arranged at the rear of the vehicle will be allowed after an inspection

- o size
- o partition situation/strength
- o layout sketch

when declaring the entry of products in the Notice, if the rear of the vehicle has a blind window or similar structure, provide relevant

- o photos
- o drawings
- o other explanatory materials

pending the introduction of the relevant standards for rural passenger vehicle models

- o other vehicles less than or equal to 7.5m in length and those longer than 7.5m in length, closed cargo space at the rear is not allowed for the time being

supplement with photos and drawings of the vehicle's internal structure as soon as possible for vehicles with blind windows at the rear of the vehicle

12. [Electric Car] – AUG 20, 2021, New Standards in Place! Electric Vehicle Embrace New Regulations

On August 20, 2021, 7 standards related to electric cars were released by the standardization committee of State Administration for Market Regulation (SAMR). Among these released standards, one is revised and the other six are newly drafted. All 7 standards will come into effect on March 1, 2022.

Basic information of the mentioned standards is as follows:

No.	Standard No.	Name	Category	Standard to be replaced
1	GB/T 31498-2021	Post-crash safety requirement for electric vehicle	National Recommending	GB/T 1498-2015
2	GB/T 4015.3-2021	Recovery of traction battery used in electric vehicle—Echelon use—Part 3: Echelon using requirement	National Recommending	Newly developed
3	GB/T 4015.4-2021	Recovery of traction battery used in electric vehicle—Echelon use—Part 4: Labels for echelon used battery products	National Recommending	Newly developed
4	GB/T 40429-2021	Taxonomy of driving automation for vehicles	National Recommending	Newly developed
5	GB/T 40432-2021	Conductive on-board charger for electric vehicles	National Recommending	Newly developed
6	GB/T 40433-2021	Technical specifications of combined power source for electric vehicles	National Recommending	Newly developed
7	GB/T 0425.1-2021	Electric vehicle top contact charging system—Part 1: General requirements	National Recommending	Newly developed

The above standards will be crucial with supporting electric vehicle development. They aim at shaping the whole sector into a safe, green and sustainable industry in different fields like product safety and energy efficiency etc.

China's focus on new energy development will offer more business opportunity for MNCs and foreign stakeholders with advanced solutions, not only in the vehicle itself, but also supporting facilities, components, software and so on.

Such standards are also a good technical guiding reference for MNCs to understand what preference or developing ideas are being implemented in the local market.

What's more, a number of foreign companies appeared in the drafting member of the standards. This means that the participation of professional MNCs or foreign companies are welcomed for the standardization. Other foreign companies, especially those who

have registered business units in China and with strong influence in the global industry, shall also have the chance to get involved with the standardization process in China.

13. [Energy Efficiency] – OCT 18, 2021, China to Strictly Regulate Energy Efficiency

On October 18, 2021, Several Opinions on Strictly Regulating Energy Efficiency and Advancing Energy Conservation and Carbon Reduction in Key Areas (hereinafter referred to as “the Opinions”) was jointly issued by the National Development and Reform Commission (NDRC) with four other national industries. These other four ministries are the National Energy Administration (NEA), Ministry of Industry and Information Technology (MIIT), Ministry of Ecology and Environment (MEE), and the State Administration for Market Regulation (SAMR).

The Opinions specify general goals for China’s energy efficiency and conservation work in two phases:

- by 2025, the proportion of energy production that reaches benchmark level is going to exceed 30 percent for key industries. Electricity utilization efficiency for data centers is also not going to exceed 1.5, and that of big data centers to not exceed 1.3.
- by 2030, further improvement is going to be made within key industries' energy efficiency base levels and benchmark levels; providing strong support to carbon peaking goals

Several key tasks are also articulated in the Opinions:

- setting industrial energy efficiency benchmark standards based on scientific methods
- referring to the admission values and qualification values of current national energy conservation standards
- strictly implementing categorized management
- reducing production capacity for over-capacity industries
- elevating entrance threshold for under-capacity industries
- eliminating backward production technology and products
- advancing energy conservation technology transformation
- strengthening market application of green technology and equipment
- enhancing construction of supporting system
- firm energy efficiency and carbon emission calculation, measuring, reporting, inspection, and evaluation mechanisms
- advancing the green development of data centers

The target key industries and data centers mainly refer to steel, electrolytic aluminum, cement, plate glass, oil refining and ethylene. China will continue to take increasingly more effective measures.

This regulation would have an impact on MNCs and foreign stakeholders in the mentioned sectors. China's determination on fulfilling the carbon peak and carbon neutrality goals will lead to further development of similar regulations on energy consumption. Rules and administrations on energy-intensive industries are likely going to be stricter to achieve the green transition. Therefore, MNCs and such sector-relevant companies are suggested to proactively act on the transition in advance to get some market advantage.

14. [Exporting to China] - DEC 1 2021, deepening reform of customs tax guarantees

General Administration of Customs (GAC)

www.customs.gov.cn/customs/302249/2480148/4026830/index.html

Abstract of the document:

GAC issued 'Notice on deepening reform of customs tax guarantees', specifying

- customs tax guarantee businesses, including
- aggregate tax guarantee
- tax maturity guarantee
- tax element guarantee

Goods export and import firms can apply for customs tax guarantee business with customs tax guarantee bond issued by financial institutions (except for firms with poor credit ratings)

For firms that fail to pay tax within the prescribed period, customs can stop providing tax guarantee business

15. [Import/Export] – DEC 13, 2021, Something Must Know About China's Customs Tariff in 2022

On December 13, 2021, State Council Customs Tariff Commission announced 2022 Customs Tariff Adjustment Plan (hereinafter referred to as "the Plan").

In the Plan, it specified that:

- Import tariff rates
 - MFN (most favoured nation) rate
 - implementing temporary import tax rate for 954 products
 - cancelling temporary import tax rate for seven IT products
 - implementing MFN rate for Republic of Seychelles and Democratic Republic of Sao Tome and Principe
 - tariff quota rate
 - continuing tariff quota management for wheat, corn, rice, grain, sugar, wool, cotton and fertiliser
 - conventional tariff
 - implementing a conventional tariff on imports from 28 countries under 17 trade agreements, including CEPA and ECFA
 - preferential tariff
 - implementing preferential tariff for 44 least developed countries
- Export tariff rates
 - continuing to implement export tariffs on 106 products including ferrochrome and yellow phosphorus
- Tariff items
 - adjusting tariff items based on '2022 harmonised trade name and coding system'

16. [ICV] – OCT 11, 2021, China ICV Take on More Actions for New Energy Vehicle

On October 11, 2021, the 3rd Conference on Innovated Global Supply Chain of NEV & ICV (hereinafter referred to as “the Conference”) was held in Nanjing. Co-sponsored by China Electric Vehicle Committee and Nanjing Municipal People's Government, the conference discussed the emerging challenges, opportunities and upgrading paths of the automobile supply chain with the theme of Automobile Supply Chain amid Global Changing and under the Goals of Carbon Emission Peak and Neutrality.

The Conference shared the latest information and technological results including project progress, achievements and visions of the "Enhance Supply Chain Plan" (a project led by China Quality Certification Centre (CQC) and China Electric Vehicle Committee of 100's, aiming at improving vehicle product design and manufacturing quality management).

A number of phased achievements of the Enhance Supply Chain Plan project were released at the meeting as well. Some achievements of this project include the following:

- 1) Established a Research and Collaborative Center for New Generation Auto Supply Chain in Jiangning district of Nanjing City.
- 2) Released a white paper report called Pain Points on New Generation Automotive Supply Chain-Automotive Semiconductors. The report was drafted by China Electric Vehicle Committee of 100 and CQC was officially released to the industry at the conference. Its aims include finding practical pain points in the supply chain, analyzing corresponding reasons and putting forward targeted implementation paths and suggestions.
- 3) The project team established an Automotive Semiconductor Cooperation Platform in conjunction with mainstream automotive enterprises, leading Tier-1 enterprises and semiconductor-related enterprises, which made its debut at the conference.

The conference also announced the establishment of the High-Quality Charging Platform, which targets exploring high-quality charging action; introducing the project progress of high-quality charging action and released the standard pilot verification results. The platform is expected to help the charging industry improving safety and service quality with testing and certification as its starting point.

The conference covered different aspects of ICV and electric vehicles. More actions and achievements are expected to be made along with the development of the project. Since many platforms or groups formed in this project are open to enterprises, MNCs and foreign companies who have entered the Chinese market are suggested to actively seize opportunity to participate. More involvement in such activities and organizations could help stakeholders understand the local market and the latest trends on ICV and relevant sectors.

If you need more information or any help on the topic, please contact:

assistant@bestao-consulting.com

17. [Green - Vehicle] – OCT 20, 2021, Critical Policy for New Energy Vehicle out for Comments

On October 20, 2021, Ministry of Industry and Information Technology (MIIT) is calling for comment on Guiding Opinions on Further Strengthening Safety Systems of NEVs (New Energy Vehicles) (hereinafter referred to as “the Draft”) until 20 Nov 2021. The Draft for comment proposes following contents:

- strengthening organizational security
- improving safety management systems

- regulating product safety design
- strengthening supply management
- strict production quality control
- improving power cell safety
- safe operational status monitoring
- hidden vehicle inspection mechanism
- enhanced operational data analysis and mining
- strengthening after-sales services
- optimization of maintenance services
- guiding consumers toward wise vehicle use
- providing emergency response services
- deepening accident investigation and analysis
- conducting problem analysis for improvement
- self-inspection mechanism
- enhanced monitoring and inspection
- better synergy among regional departments

The Draft also includes measures for a NEV safety monitoring platform. The call-for-comment period has finished and BESTAO will keep following-up on further news.

18. [Medical] – DEC 16, 2021, Medical Attention Required! China Released Eight New Medical Principles

On December 16, 2021, National Medical Products Administration (NMPA) released eight medical device guiding principles, including

Registration Guiding Principles on Passive Surgical Instruments Under Arthroscopy

Registration Guiding Principles on Single-Use Ureteral Introducer Sheaths

Registration Guiding Principles on Orthodontic Filaments

Registration Guiding Principles on Single-Use Minimally Invasive Fascial Closure Devices

Registration Guiding Principles on Anaesthesia Mask Products

Registration Guiding Principles on Non-Vascular Luminal Guidewire Products

Registration Guiding Principles on Circumcision Staplers

Registration Guiding Principles on Dental Desensitisers

If you need more information or have any question on the principles, please contact:

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19. [Import/Export] – DEC 13, 2021, Catalogue for Key Technologies and Equipment Import Updated by 5 Ministries

On December 13, 2021, Ministry of Industry and Information Technology (MIIT), along with General Administration of Customs (GAC), Ministry of Finance (MoF), National Energy Administration (NEA), State Administration of Taxation (SAT), released Notice on Adjusting Catalogues for Key Technologies and Equipment Import Tax Policies (hereinafter referred to as “the Notice”).

The Notice contains main contents as follows:

- ***Catalogue for national key technology equipment and products (2021), Catalogue for component and raw material of key technology equipment and products (2021) and Catalogue for key technology equipment and products not qualified for tax exemptions (2021)*** will be implemented from January 1, 2022

- ***Catalogue for national key technology equipment and products (2021) and Catalogue for component and raw material of key technology equipment and products (2021)*** cover:

- large clean, efficient power generators
- ultra-high voltage power transmission and transformation equipment
- petroleum and petrochemical equipment
- mining equipment
- shipping and ocean engineering equipment
- high-speed rail and urban rail transit
- large construction equipment and special infrastructural equipment
- new textile machine models
- new and high power agriculture equipment
- electronic information and bio-pharmaceutical equipment
- civil-use aircraft and its engines and equipment
- basic component for key technology equipment

20. [Radio] – DEC 24, 2021, New Radio and Space-related License Management Document Calling for Comments

On December 24, 2021, Ministry of Industry and Information Technology (MIIT) is calling for comment until January 30, 2022 on four sets of radio management and space-related services administrative license application materials.

The four documents are:

- Satellite Radio Frequency Usage License
- Space Radio Stations Setup and Usage Administrative License
- Satellite Communication Network Radio Frequency Administrative License
- Satellite Ground Station Setup and Usage Administrative License

BESTAO Reviews and Translations

21. [BESTAO Translation] - MAR 12, 2021, New Registration Requirements Released for Medical Device Master Files

On March 12, 2021, the National Medical Products Administration (NMPA) issued the Announcement on Registration of Medical Device Master Files. It went into force immediately following its announcement.

The medical device master file registration system has been established in likeness to the Opinions of the State Council on Reforming the Review and Approval System for Pharmaceuticals and Medical Devices (No. [2015] 44, issued by the State Council). It aims to further improve the quality of medical device review and approval. This could establish a more scientific and efficient review and approval system, as well as protect the business secrets of various enterprises.

For MNCs and foreign investors of medical devices, the new registration requirement for the medical device master file will apply to nearly all market approvals (registration, modification, clinical trial etc.) for Type II and Type III imported medical devices in the Chinese

market. It's necessary to dig into the new documents and make adjustments to their existing master file registration system if needed.

BESTAO has translated the complete content of the Announcement and its annexes. The full text of these documents contains 2860 English words and 15 pages.

Please check the following link for further information, and Chinese version is also available on our regulatory library:

English version:

<http://www.bestao-consulting.com/translated/detail/566>

Chinese version:

<http://www.bestao-consulting.com/translated/detail/567>

If you need more information, or any help on the topic, please contact:

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22. [BESTAO Translation] - OCT 10, 2021, Outline for National Standardization Development

On October 10, 2021, general offices of the Communist Party of China Central Committee and the State Council issued the Outline for National Standardization Development (hereinafter referred to as “the Outline”). The Outline states the general planning of China’s standardization and goals until 2035.

Background:

- On March 11, 2015, the State Council issued Deepening Reform of the Work of Standardization. It is a national-level document for standardization, which depicts the focus of China’s standardization development into three phases for the next six years (2015-2016 Phase I; 2017-2018 Phase II; 2019-2020 Phase III).
- Further high-level strategies that focus on standardization after 2020 have been expected by all stakeholders since 2020.

Current Status and Facts:

- The guiding principles of the Outline include:
 - 1) Optimize standard administration structure;
 - 2) Improve standardization management efficiency;
 - 3) Enhance participation in international standardization affairs;
 - 4) Establish a standardization system with higher development quality.
- The Outline’s development goals are in two phases:
 - 1) By 2025, standardization will achieve several transitions: from purely government-led to driven both by the government and market; from solely domestic to mutually domestic and international promotion; from industry and trade to the entire economy and society (governance); from a quantitative scale to quality and benefit.
 - 2) By 2035, standardization in China will have an optimized structure, as well as a more advanced and globalized system. This system will be driven by the market, led by the government, and participated in by the whole society and enterprises.
- Supporting measures of the Outline:

- 1) Optimizing managing capability and working process on both national and provincial levels.
- 2) Supporting standardization development with financial, talent and technological policies and resources.

Next Steps and Possible Impact:

- More international standards are expected to be adopted and converted in China. These will reduce the difficulty of compliance work for MNCs along with global companies first entering the Chinese market.
- The Outline encourages the development of “association standards” and assigns them with a bigger role in the standardization of China. This means key industry players will start to lead many standardization efforts, and “association standards” will, more often than ever, be adopted by higher levels of standards.
- Possible opportunities for foreign institutes and enterprises with cutting-edge green technologies include participation in the standard development process, as China will develop and revise green-related standards as an implementation of the Outline.

The standard development work involving high-tech and ICT industries (AI, big data, blockchain, new energy, ICVs, etc.) may boom in the coming years. Foreign stakeholders that are already in the Chinese market for these sectors should be aware of potentially rapid changes with regulatory and compliance actions.

BESTAO team has translated the complete file in English, with 5032 English words and only for 26 euros. Please check the following link for the full text:

<http://www.bestao-consulting.com/translated/detail/790>

About BESTAO Consulting

Founded by senior experts with solid industry experience, BESTAO Consulting provides regulatory compliance solutions across a wide range of industries to our global clients who wish to enter Chinese markets. Our areas of expertise include Government Affairs, Industry Policies, Technical Standards and Regulations, Certification and Market Access, and Translation Services.

Accessing the Chinese market has become increasingly more important for overseas companies of all kinds and having a better understanding of the requirements to enter this large and complex market will give you the advantage over your competition. BESTAO Consulting can help you understand the Chinese regulatory environment to quickly and effectively gain access to the Chinese Market.

What We Offer:

- The government affairs team supports our clients in identifying key stakeholders in China to build connections and improve business development.
- Our consulting team helps our clients understand China's legal framework, technical regulations, standardization system and certification schemes, including but not limited to CCC, China RoHS, Medical Device Registration, and Special Equipment Certification. We advise our clients on market access requirements and draw comparisons between EU/US and China.
- Our intelligence collection team gathers up-to-date information on China's technical regulations and standardization in areas such as China Energy Labelling scheme, Green Design and Manufacturing policies, and Regulation Development of New Energy Vehicles, etc. We make sure that our clients stay informed on the latest developments in regulation and standardization.
- Our training team is dedicated to conducting workshops for Overseas companies on understanding key China Technical Regulations to facilitate their entry into Chinese markets.
- Our translation team provides high-quality English translation of laws and regulations, standards, and technical specifications.

For more information on how BESTAO can help your company enter and grow in the Chinese market, please contact us at

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